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14. ABSTRACT
In *Project 1*, we are adapting and empirically evaluating a safety plan intervention targeted at suicidal military service members receiving care at the Walter Reed National Military Medical Center. Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. As of 9/24/2012, 67 participants out of the 186 expected have been enrolled. In *Project 2,* we are examining the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at high suicide risk at VA Emergency Departments (ED). Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit, as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post index ED visit. As of 9/24/2012, 284 participants out of the 600 expected have been enrolled across sites.

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Suicide Prevention, Safety Planning, Acute Care, Inpatient Treatment

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Introduction

The Army Suicide Event Reporting (ASER) and the Total Army Injury and Health Outcomes Database (TAIHOD) systems have indicated increasing rates of suicide among Active Army, Guard, and Reserve units over the last several years. Additionally, research has indicated that veterans are more than twice as likely to kill themselves as compared to the general population. There are limited evidence-based suicide prevention interventions that have been developed for military personnel and veterans who are experiencing suicide ideation or who have made a suicide attempt. The objective of the research described in this annual report is to adapt and evaluate a brief, readily accessible, and personalized intervention, safety planning, that aims to reduce suicide risk in military and veteran populations in three ways by: (1) evaluating suicide risk using a structured assessment measure; (2) enhancing suicide-related coping strategies; and (3) increasing acceptability and initiation of appropriate mental health and substance use treatments. This research is unique in that the intervention, safety planning, is being evaluated in both military and VA settings, with the aim of disseminating related educational materials to both military and VA patients and providers. The specific aims are to evaluate the efficacy of the safety planning intervention on suicide ideation, suicide-related coping, and attitudes toward help seeking for hospitalized military personnel at *high risk* for suicide and to evaluate the effectiveness of the safety planning intervention on suicide attempts, suicide ideation, attendance of outpatient mental health and substance abuse interventions, and suicide- related coping for veterans at high suicide risk in emergency department (ED) settings. Two separate, but related projects are being conducted to compare the study intervention with enhanced usual care conditions on suicide-related outcomes. In *Project 1*, the safety planning intervention has been adapted for military service members who are at high risk for suicide. A randomized controlled trial is being conducted to determine the efficacy of the safety planning intervention for hospitalized military personnel at the Walter Reed National Military Medical Center (formerly Walter Reed Army Medical Center). Outcomes include suicide ideation, suicide-related coping, and attitudes toward help seeking at discharge, 1-month, and 6-months post discharge. In *Project 2,* a quasi-experimental design is being used to examine the effectiveness of a comprehensive intervention including the safety plan intervention and follow-up care, for veterans at *high risk* for suicide at VA ED. Outcomes include suicide attempts, suicide ideation, and suicide-related coping at 1, 3, and 6 months following the index ED visit as well as attendance at an outpatient mental health or substance abuse treatment appointment within 30 days post the index ED visit. If the safety plan intervention is determined to be effective, then this intervention may be widely and quickly disseminated in the DoD and VA settings through publications and presentations using a variety of multi-media platforms. The ultimate goal of the safety plan dissemination initiative is to provide clinicians and other professionals who work with high risk military service members and veterans with a brief, easily administered intervention that is designed to mitigate suicide risk.

Body

During Year 3 of this project, extensive work has continued to be put into securing additional approvals from all the institutional regulatory boards (IRBs) that have oversight on the implementation of both Project 1 (SAFEMIL) and Project 2 (SAFEVET). In addition, our team has met all reporting guidelines for 19 regulatory agencies and obtained timely approvals on amendments as well as annual reviews. Recruitment of participants for SAFEMIL has progressed at the Walter Reed National Military Medical Center (WRNMMC) for Project 1 and as of September 24, 2012, a total of 67 participants out of the expected 186 (i.e., 36%) have been recruited. In addition, we are currently in the process of securing IRB approvals to begin recruitment at a second military site, the Ft. Belvoir Community Hospital. Recruitment of participants for SAFEVET has progressed at all the control sites while all the intervention sites have ended recruitment. A total of 284 participants out of the expected 600 (i.e., 47%) have been recruited. Follow-ups for the study participants in SAFEMIL and SAFEVET are in progress. The study PIs have been meeting at least once a week to discuss study objectives, methodology, timeline, and individual responsibilities in addition to problem solve implementation related challenges. Discussions are documented in weekly *Meeting Minutes*. The first quarter focused heavily on the adaptation and submission of study amendments and Project 2 prepared control sites for the beginning of recruitment at their sites. The second and third quarter continued to focus on the preparation and submission of IRB regulatory-related materials and required amendments across study sites and assurances that all Data Use Agreements were complete and approved so processes to combine data from all Project 2 sites could commence. During the final three quarters, participant enrollment began at the four SAFEVET control sites and participant enrollment and follow-ups have remained a continued focus for both Project 1 and Project 2. In addition, we have submitted a no-cost extension for both projects to allow for continuing participant enrollment and follow-up. At many study-sites, lengthy initial regulatory review processes delayed the beginning of recruitment and as a result, participant enrollment has been lower than expected. In September 2012, a no-cost extension was formally requested from the study sponsor. We anticipate that the no-cost extension will allow for a sufficient number of participants to be enrolled over the course of the upcoming year. A detailed summary of the progress for each project is detailed below.

Key Research Accomplishments

For the 3rd year reporting period, here is a listing of all activities associated with SAFEMIL and SAFEVET.

Section I – SAFEMIL Progress
Safety Planning for Military (SAFE-MIL) - Walter Reed National Military Medical Center

1. Enrollment and Participant Follow-Up
As of September 24, 2012 (the end date for the current Annual Report), we have enrolled 67 participants in the SAFEMIL study (61 participants have been enrolled in the past year – see Appendix E). We began conducting follow-up assessments with participants on September 29, 2011. Thus far, we have successfully completed 43 one-month follow-up assessments and 26 participants have completed the study.

2. Participant Attrition Due to Incarceration
Participant 306, who was enrolled on September 21, 2011, has been dropped as a direct result of federal incarceration. This decision was made after discussion between study PIs and after receiving direct guidance to drop the participant from HRPO as well as the WRNMMC and USUHS IRB boards.

3. Amendment of Original IRB Protocol and Consent Form
The research team has worked on a number of modifications to the original protocol and consent form. These changes are a direct result of the merger between the Walter Reed Army Medical Center and the National Naval Medical Center, and as a result of ongoing discussions between the IRB staff at the newly formed Walter Reed National Military Medical Center and Uniformed Services University of the Health Sciences (USUHS). These changes included modifications to the protocol and consent form with updated addresses and telephone numbers for the many study personnel who had relocated their offices after the aforementioned merger. We have also replaced all references to the former Walter Reed Army Medical Center (WRAMC) with the current title, "Walter Reed National Military Medical Center" (WRNMMC). Further, the merger caused us to reevaluate our data storage policies. We were previously storing participant research records at the WRAMC inpatient psychiatric unit. In our most current amendment, we requested and were approved to permanently store the participant research records in a locked cabinet in a locked office at Dr. Holloway's Laboratory (study contact PI) at USUHS, Department of Medical and Clinical Psychology, so we could ensure the effective monitoring, regulation, and access to study documentation and data. Finally, we modified several measures which are administered to study participants. For example, in our demographics form we modified the religious and race-reporting categories to make them more inclusive and consistent with standards utilized for the 2010 U.S. census report. We also added additional categories to our demographics form to access for homelessness and the participant's personal and familial psychiatric history. Clinical researchers felt it was important and pertinent to update this information to not only capture more information, but to also help assess for current and potential risk factors.

The full amendment packet containing all of the above revisions was submitted to the WRNMMC IRB on November 13, 2011. We received feedback from the WRNMMC IRB on December 13, 2011 indicating that we needed to provide confirmation of the appointment of our new Medical Monitor (see item 7 below). We provided this confirmation on December 20, 2011 and the WRNMMC IRB subsequently approved our revised amendment on December 22, 2011. The USUHS IRB provided secondary concurrence on January 3, 2012.

4. Continuing Review Approval from the WRNMMC IRB, the USUHS IRB, and HRPO
We submitted our continuing review report to the WRNMMC IRB on November 13, 2011, one month prior to the expiration date of our previous continuing review approval from the WRNMMC IRB, which was December 13, 2011. The WRNMMC IRB formally met and reviewed our continuing review report

on December 15, 2011. However, because this was two days after the expiration date of our previous study approval, the WRNMMC IRB required us to temporarily stop all study-related activities including recruitment as of December 13, 2011 until they approved our recently submitted continuing review. We resumed all study-related activities on December 22, 2011 after the WRNMMC IRB provided official approval for our study for the subsequent 12 months to expire on December 14, 2012. We forwarded confirmation of this approval to the USUHS IRB and obtained their secondary concurrence on December 22, 2011.

5. Development of Patient Flyer and Physician Referral Guide
We developed a patient flyer and a referral guide for physicians, specific to the SAFEMIL study, in order to increase recruitment to the study. The patient flyer is currently ready for IRB review and will be utilized once we receive IRB approval.

6. "Contact Us" Letter Developed
In an effort to boost our retention rates, we have developed a "contact us" letter that we will send to participants whom we have had a difficult time reaching for 1-month and 6-month follow-up assessments. This letter asks that the participant contact study staff to update contact information so that the next assessment may be scheduled. A template of this letter is ready for IRB review and will be submitted early in the next quarter.

7. Ft. Belvoir Being Added as Recruitment Site
We are in the process of adding Fort Belvoir Community Hospital, located in Fort Belvoir, VA, as a second recruitment site for the study in order to boost participant enrollment. We have completed the initial submission packet and anticipate that it will be submitted to the Fort Belvoir IRB early in the next quarter. We have kept track of weekly patient census at Ft. Belvoir to have a sense of how many patients we can potentially expect as a result of implementation of the study at this 2nd site.

8. New Study Medical Monitor
Dr. Edward Swanton, our previous medical monitor left his position at WRNMMC abruptly due to the institutional hiring freezes and delays associated with his hiring as a civilian employee. His replacement, Dr. Russell Carr, is a Navy psychiatrist employed at WRNMMC with years of experience in inpatient psychiatry. He recently wrote a peer-reviewed manuscript summarizing his experiences with suicide during the time of his deployment. Given his clinical experience and also regulatory work with the WRNMMC IRB as a full member, we believe that he is the perfect fit for this position and we are very appreciative of his agreement to serve in this capacity.

9. New Study Clinical Coordinator and Study Staff
On March 21, 2012, Dr. John Dennis, the study's Clinical Coordinator, left USUHS to engage in full-time civilian private practice. The SAFEMIL Clinical Coordinator position was assigned to Dr. Jaime T. Carreno-Ponce, a Licensed Psychologist who has previously worked as a Postdoctoral Fellow on the project. In addition, we have added two Postdoctoral Fellows, Kasaan Holmes (MA American University) and Lauren Matthews (MA The Chicago School of Professional Psychology) and a new USUHS Clinical Psychology PhD student, Jessica MacIntyre, who will assist with recruitment, enrollment, consenting, and baseline assessment endeavors.

10. Data and Safety Monitoring Board (DSMB)
We are in the process of organizing a DSMB for the project. As of 9/24/12, initial invitations have been sent out to 3 candidates. We anticipate that the DSMB membership will soon be complete and the initial meeting of the DSMB will occur in the next quarter.

11. Data Sharing Agreements (DSA)
At the request of our IRB, we have written a DSA with the Armed Forces Health Surveillance Center (AFHSC). The DSA has been submitted and received for approval and we anticipate that the DSA will be in place soon.

12. Certificate of Confidentiality
After initial IRB Approval for the study was obtained from the WRNMMC IRB, USUHS IRB, and HRPO, we applied for a study-specific Certificate of Confidentiality from the National Institutes of Health (NIH). After a lengthy processing delay, we were awarded the Certificate, which is currently on fine and valid until study completion.

13. Began Transporting All Study-Related Documentation in a Locked Briefcase
Based on discussions within the SAFEMIL treatment team and guidance from the WRNMMC IRB, a decision was made to transport all study related documentation obtaining personally identifiable information to and from the hospital and the research office in a locked briefcase. We hope that by implementing this practice, study-related security and confidentiality will be subsequently strengthened.

14. Finalized the SAFEMIL Master Database
A comprehensive database was developed and finalized in the fourth quarter of FY2011. It is being utilized for the following functions: (1) recruitment, screening, and enrollments reports, (2) assessment protocol instructions and detailed instructions for administering the assessment measures, (3) collection of data from assessment interviews, (4) scheduling and tracking of assessment appointments and contact information, (5) tracking and reporting of adverse events, and (6) information to facilitate risk management. A great benefit of this database is that it ensures that all study assessment measures are being administered, scored, and interpreted in a standardized way. We have had our study laptops encrypted with DoD encryption software and have begun data entry.

15. Conducted Monthly SAFEMIL/SAFEVET Raters' Calls
A monthly call was set up to for all SAFEMIL and SAFEVET assessors for the purpose of providing ongoing training and consultation in study assessment procedures to ensure standardization of the delivery and scoring of all study assessment measures. This monthly call, which all SAFEMIL and SAFEVET assessors are required to attend, is organized and supervised by Dr. Barbara Stanley from Columbia University. Recently, these calls have focused on discussions regarding the classification of questions concerning primary outcome measures in suicidal patients.

16. Made Entries to the Patient Medical Record
Per recommendations from the WRNMMC IRB, we are now required to document behavioral observations within participant medical records to document our research contact with participants. The purpose of such documentation is primarily for research staff to (a) maintain their credentials as stipulated by the Credentialing Program at WRNMMC, and (b) to allow research and treatment teams to work together more effectively and provide a complete battery of psychological and support services to patients involved in the SAFEMIL study. A template for these observations was included in the amendment that was approved by the WRNMMC IRB. We have also revised the language in the consent form to alert potential participants that we will be documenting these basic observations.

17. Participated in November 9, 2011 Training with Dr. Gregory Brown
On November 9, 2011, Dr. Gregory Brown of the University of Pennsylvania facilitated a half-day Safety Planning Intervention training. This was the second and final training of a series of two Safety Planning Intervention Trainings given to USUHS study-related staff members. The first session was facilitated by Dr. John Dennis in FY2011. During the November 9, 2011 session, assessors and therapists listened to several de-identified Safety Planning sessions from previous study participants and provided feedback to study providers.

18. Updated Study Safety Plan
Per the suggestions of Dr. Gregory Brown, the developer of the Safety Plan, we made several updates to the SAFEMIL Safety Plan. We have rearranged the numbering in section 5 of the Safety Plan, which lists professionals or agencies that participants can contact if they are having a suicidal crisis. For example, the first two contacts listed are now Clinicians with whom the participants are familiar with and individuals who could provide therapeutic assistance and crisis mediation if necessary. We have also added the contact information for Military One Source, which provides free, confidential counseling services to military personnel. In addition, we developed a prototype for a small, wallet-sized version of the SAFEMIL Safety Plan. The wallet-sized version lists coping strategies and professional contacts that participants can utilize if they are having a suicidal crisis. We believe that this portable version of the Safety Plan can be more readily accessible to study participants. We are currently working to have a small number of these pocket-sized plans printed and we plan to begin providing them to participants during the next quarter.

Section II – SAFEVET Progress
Safety Planning for Veterans (SAFEVET) – VA Emergency Departments

1. Obtained Initial Regulatory Approval from HRPO for the Following VA Site:
San Diego VAMC

2. Obtained Continuing Review Approvals from the Following VA IRBs:
Denver VAMC, Manhattan VAMC, Philadelphia VAMC, Portland VAMC, Milwaukee VAMC, Bronx VAMC, Canandaigua VAMC (Syracuse VAMC IRB), San Diego VAMC, and Long Beach VAMC

3. Obtained Continuing Review Approval from the Chesapeake IRB and HRPO for the Following VA Sites:
Denver VAMC, Manhattan VAMC, Philadelphia VAMC, Portland VAMC, Milwaukee VAMC, Bronx VAMC, Canandaigua VAMC, San Diego VAMC, and Long Beach VAMC

4. Enrollment and Follow-up

a. Bronx VAMC
Enrollment began at the Bronx site on 2/22/2012 and 13 participants have been enrolled. Enrollment and follow-up continues at this site with data being collected by assessors at the Manhattan VAMC.

b. Denver VAMC
In Denver, recruitment ended on 8/3/2012 when the goal of 75 participants enrolled was achieved. Data collection continues and is projected to conclude in February 2013. As of the end of year 3, Denver staff has recruited 75 participants (46 in the past year). Twenty four participants have completed the study. Follow-up continues at this site.

c. Long Beach VAMC
Enrollment began at the Long Beach site on 3/29/2012 and 33 participants have been enrolled. Enrollment and follow-up continues at this site with data being collected by assessors at the Denver VAMC.

d. Manhattan VAMC
Enrollment began at the Manhattan site in December 2010 and continued in Year 3, 53 participants have been enrolled (25 in the past year), and 10 participants have completed the study. Enrollment will end at the end of September 2012. Follow-up continues at this site.

e. Milwaukee VAMC
Enrollment continued at the Milwaukee site in Year 3, 34 participants have been enrolled (33 in the past year), and 7 participants have completed the study. Enrollment and follow-up continues at this site with data being collected by assessors at the Philadelphia VAMC.

f. Philadelphia VAMC
Enrollment continued at the Philadelphia site in Year 3, 62 participants have been enrolled (24 in the past year), and 23 participants have completed the study. Enrollment will end at the end of September 2012. Follow-up continues at this site.

g. Portland VAMC
Enrollment began at the Portland site on 11/1/2011, 13 participants have been enrolled, and 1 participant has completed the study. Enrollment at this site was ended on 8/3/2012. Follow-up continues at this site and is being conducted by assessors at the Canandaigua VAMC.

h. San Diego VAMC
Enrollment began at the San Diego site on 9/3/2012 and 1 participant has been enrolled. Enrollment and follow-up continues at this site with data being collected by assessors at the Canandaigua VAMC.

5. Coordinated with Long Beach Control Site – Denver VA
The Denver site continues to collaborate with the Long Beach site behind the VA firewall to facilitate the secure sharing of data. Denver assessors continue to complete baseline and follow-up assessments for participants recruited at the Long Beach site.

6. Coordinated with Portland SAFEVET Site and San Diego Control Site – Canandaigua VA
The Canandaigua VA continued to be primary liaison to the Portland, Oregon, VAMC active site, as well as the San Diego, CA, control site for SAFE VET. Canandaigua study staff conducted follow-up telephone assessments of study participants enrolled at both sites over the past year. Canandaigua PIs continued to provide oversight and to field day-to-day operational questions from the two sites. Portland IRB was provided with continuing review documents, and San Diego IRB approval was obtained. Study staff was hired, and protocols for transfer of clinical information between Portland and Canandaigua were finalized and put into place. Final San Diego VAMC approval was obtained August 24 2012, and their first subject was recruited on September 17, 2012. Enrollment at Portland was limited by the unexpectedly high percentage of moderate-risk suicidal veterans who are admitted to inpatient services. Since few were discharged from the emergency department, the numbers eligible for enrollment are lower than anticipated. During the proposed NCE period, new subjects will be recruited at the San Diego control site only.

7. Coordinated with Bronx Control Site – Manhattan VA
The Manhattan VA continued to collaborate with the Bronx VAMC control site. The Manhattan staff conducted baseline and follow-up assessments with participants enrolled at the Bronx site.

8. Coordinated with Milwaukee Control Site – Philadelphia VA
The Philadelphia VA continued to collaborate with the Milwaukee VAMC control site. Philadelphia staff conducted baseline and follow-up assessments with participants enrolled at the Milwaukee site.

9. Participant Engagement and Retention Strategies
The Philadelphia site created a brief report on strategies to facilitate participant engagement and retention.

10. Initial and Continuing Rater Training
CUMC took responsibility for the evaluation of rater training tapes and gave verbal and written feedback to all assessors for the project. Columbia University maintains responsibility for training and evaluation of rater training tapes. Verbal and written feedback has been given to all assessors for the project. A monthly raters' meeting is held. This meeting is organized and chaired by Dr. Stanley. We have trained four new raters over the past year. In addition, we have discussed several suicide-related events and reached consensus on their classification. Dr. Stanley serves as the liaison between the PI Steering Committee and the Raters Committee.

11. Weekly PI Telephone Meetings
All Executive committee PIs participated in weekly telephone meetings to discuss coordination of the study across all sites and to address emergent issues.

12. Monthly Assessor Telephone Meetings
Dr. Stanley leads monthly assessor calls with study assessors. Study assessors at each assessment site participated in these calls to discuss assessment strategies and to troubleshoot any difficulties.

13. Control Site Telephone Meetings
Dr. Currier leads monthly telephone conference calls with Control Site leads and study staff to provide guidance to and coordination with these sites, and to troubleshoot difficulties experienced by the control sites.

14. Study Coordination
The MOMRP Study Coordinator (operating out of the Philadelphia site) assisted all sites with completing continuing review and amendment submissions and coordinated sites' continuing review submissions to Chesapeake IRB and HRPO; advised sites on local SAE reporting requirements, disseminated local SAE reports to all MOMRP sites, provided guidance to all sites on reporting of external SAEs, and coordinated the submission of SAE reports to Chesapeake IRB and HRPO as required; tracked all sites' current IRB due dates and status of sites' continuing reviews and amendment submissions; provided guidance and quality control to all assessment sites regarding the assessment database; helped SAFEMIL staff troubleshoot data entry errors and provided guidance on cleaning data; tracked all sites' screening, enrollment, participant follow-up, and adverse events, created report, and reported to project PIs on weekly basis; created a spreadsheet to track all sites' projected enrollment at end of the performance period. In addition, each SAFEVET Assessment site assisted their respective paired Control site with regulatory documentation.

15. Completed Data Use Agreements
The Philadelphia site assisted all sites in creating Data Use Agreements (as required) for future merging of databases.

16. New Assessors Hired
At the Philadelphia and Manhattan sites, new back up assessors were hired, trained and credentialed. At the Denver site, a new assessor was hired and is in the process of being trained and credentialed.

17. Obtained SAFE VET Monthly Reports
All SAFE VET intervention sites submitted monthly reports regarding suicide-related variables in the VA EDs and follow-up information from the VA medical records. Activities of the Acute Services Coordinators are also provided in a monthly report.

18. Completed Veteran Key Informant Interviews
In April 2011, funds were allocated to conduct Veteran key informant interviews with Veterans who participated in SAFE VET. One hundred Veteran interviews and fifty staff interviews were conducted and summarized in a report to the VA.

19. Audit of Informed Consent Documents at the Denver VAMC site
In July 2012 the Denver VA Research Compliance Officer conducted an audit of 44 VA informed consent documents and HIPAA Authorization Forms signed from 4/15/11 to 3/31/12 for this study. No compliance issues were found when reviewing the signed consents or HIPAA authorization forms for these subjects.

20. Review of Philadelphia Site by VA North East Regional Oversight (NERO) committee
A review of the project at the Philadelphia site was conducted by the NERO committee on June 13, 2012, and the site received excellent feedback regarding their study organization and documentation of IRB materials.

Reportable Outcomes

- **Peer Reviewed Manuscripts**

Knox, K., Stanley, B., Currier, G., Brenner, L., Ghahramanlou-Holloway, M., Brown, G. (2012). An emergency department-based brief intervention for Veterans at risk for suicide (SAFE VET). American Journal of Public Health, 102(S1), S33-S37.

- **Presentations**

Brown, G., Ghahramanlou-Holloway, M., Knox, K., McKeon, R., & Stanley, B. (2012, April). SAFEMIL: Randomized controlled trial to test the efficacy of a brief Safety Planning intervention. In G. Brown (Moderator), Brief interventions to reduce suicide risk for military servicemembers and Veterans in acute care settings. Symposium presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.

Brown, G.K., Stanley, B., Holloway, M. (2012, April). Brief interventions to reduce suicide risk for military service members and Veterans in acute care settings. Symposium presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.

Ghahramanlou-Holloway, M., Fitek, D., Joiner, T., Jobes, D., & Rudd, D. (2012, April). Review of funded DoD suicide prevention inpatient psychotherapy clinical research trials. In P. Gutierrez (Moderator), Status of Department of Defense funded suicide research. Symposium presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.

Stanley, B. (2012, April). Brief interventions for suicidal patients in multiple care settings. Workshop presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.

Currier, G., & Ghahramanlou-Holloway, M. (2012, May). A brief intervention to reduce suicide risk in military service members and Veterans. Invited presentation at the United States Medical Research and Materiel Command 'In Progress Review' Meeting, Fort Detrick, MD.

Stanley, B., Brown, G. K., Ghahramanlou-Holloway, M., & Brenner, L. (2012, June). Safety planning intervention to reduce suicide risk among military personnel and Veterans. Symposium presented at the Annual Department of Defense and Veterans Administration Suicide Prevention Conference, Washington, DC.

Ghahramanlou-Holloway, M., Castro, C., Fitek, D., & Jobes, D. (2012, June). DoD funded inpatient psychotherapy randomized controlled trials for the prevention of suicide. In P. Gutierrez (Moderator), Status of Department of Defense funded suicide research. Symposium presented at the Annual Meeting of the American Association of Suicidology, Baltimore, MD.

Ghahramanlou-Holloway, M. (2012, August). Laboratory for the treatment of suicide-related ideation and behavior: Organization and current activities. Invited presentation at the Defense Suicide Prevention Office, Staff Educational Series, Arlington, VA.

Ghahramanlou-Holloway, M. (2012, September). Managing suicidal behaviors. Invited webinar presented with Dr. Peter Gutierrez, organized by the Defense Centers of Excellence for Psychological Health and Traumatic Brain Injury, podcast available by visiting (http://www.dcoe.health.mil/Training/MonthlyWebinars/2012Webinars.aspx)

Conclusion

For SAFEMIL, the third year has been focused on participant recruitment and follow-up, writing and submitting amendments to the study, refining the study and recruitment procedures, and personnel transition. As of September 24, 2012, we have enrolled 67 participants into the SAFEMIL study, 26 of these participants have completed the study and 39 remain active in the study. Of these enrolled, 61 have been enrolled since the time of the last annual report (see Appendix E for Consolidated Standards of Reporting Trials [CONSORT] diagram since last annual report).

Regarding the SAFEVET study, the third year focused on obtaining appropriate regulatory approvals and hiring study personnel at Control sites, coordinating activities between Assessment sites and their paired Control sites, and on patient recruitment and follow-up at all sites. Four sites began recruitment in Year 3. As of September 24, 2012, 284 participants had been enrolled into the SAFEVET study across all eight sites, 65 have completed the study and 105 participants remain active in the study. In the past year, 188 participants have been enrolled and 52 have completed the study.

This study represents the only combined efficacy and effectiveness trial addressing the needs of military personnel and veterans following a suicidal crisis. Given the magnitude of the public health problem presented by suicide-related ideation and behaviors in the military, there is a significant need for empirically supported treatments that directly address the needs of this at high-risk individuals.

References

None.

Appendices

Appendix A: IRB Related Progress for SAFEVET and SAFEMIL Projects

Appendix B: SAFEVET Enrollment Report and Adverse Event Log

Appendix C: SAFEMIL Enrollment Report and Adverse Event Log

Appendix D: SAFEVET and SAFEMIL Participants Lost to Follow-up

Appendix E: SAFEMIL CONSORT Diagram, Since Last Annual Report

Appendix F: SAFEMIL Baseline Demographic Data

Appendix G: SAFEMIL Baseline Suicide Attempt Data

APPENDIX A
IRB Related Progress for SAFEVET and SAFEMIL Projects

IRB	Site #1 Bronx VAMC CONTROL	Site #2 Canandaigua VAMC ASSESSMENT SITE[1]	Site #3 San Diego VAMC CONTROL	Site #4 Denver VAMC SAFEVET	Site #5 Long Beach VAMC CONTROL
Site PI	Leo Sher	Glenn Currier Kerry Knox	Kathleen Kim	Lisa Brenner	Lawrence Albers
VA IRB	Approved 12/2/2010 CR Approved: 11/20/2011	Syracuse IRB Approved 1/3/2011 CR Approved: 11/21/2011	Approved 3/3/2011 CR Approved: 2/16/2012	Approved 5/7/2010 CR Approved: 2/22/2012	Approved 6/9/2011 CR Approved: 4/30/2012
PI Institutional IRB	NA	NA	NA	NA	NA
Chesapeake IRB	Approved 5/25/2011	Approved 4/5/2011	Approved 7/6/2011	Approved 9/09/2010	Approved 8/31/2011
HRPO	Approved 6/21/2011 HRPO A-15768.h	Approved 5/25/2011 HRPO A-15768.f	Approved 6/25/2012 HRPO A-15768.i	Approved 9/14/2010 HRPO A-15768.a	Approved 9/20/2011 HRPO A-15768.j
Other IRB	NA	NA	NA	NA	NA
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk
SAMPLE SIZE	N = 75 at BVAMC	N = 75 at CVAMC	N = 75 at SDVAMC	N = 75 at DVAMC	N = 75 at LBVAMC

[1] Assessment Center for San Diego and Portland VAMCs

IRB	Site #6 Manhattan VAMC SAFEVET	Site #7 Milwaukee VAMC CONTROL	Site #8 Philadelphia VAMC SAFEVET	Site #9 Portland VAMC SAFEVET	Site #10 WRAMC SAFEMIL
Site PI	Christie Jackson	Bert Berger	Gregory Brown	Lauren Denneson	Marjan Holloway
VA IRB	Approved 5/3/2010 CR Approved 3/13/2012	Approved 2/15/2011 CR Approved 2/6/2012	Approved 5/12/2010 CR Approved: 2/15/2012	Approved 11/3/2010 CR Approved: 7/6/2012	NA
PI Institutional IRB	NA	NA	NA	NA	USUHS (SAFEMIL ONLY) Approved 12/22/2011
Chesapeake IRB	Approved 6/17/2010	Approved 4/5/2011	Approved 8/09/2010	Approved 1/31/2011	NA
HRPO	Approved 9/24/2010 HRPO A-15768.b	Approved 5/25/2011 HRPO A-15768.g	Approved 9/02/2010 HRPO A-15768.c	Approved 2/28/2011 HRPO A-15768.d	Approved 2/17/2012 HRPO A-15768.e
Other IRB	NA	NA	NA	NA	WRNMMC Approved 12/22/2011
RISK	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	No Greater than Minimal Risk	Greater than Minimal Risk
SAMPLE SIZE	N = 75	N = 75	N = 75	N = 75	N = 186

CR = Continuing Review; CIC = Clinical Investigations Committee; HRPO = Human Research Protections Office; HUC = Human Use Committee; USUHS = Uniformed Services University of the Health Sciences; VAMC = Veterans Affairs Medical Center; WRAMC = Walter Reed Army Medical Center

APPENDIX B
SAFEVET Enrollment Report and Adverse Event Log (As of September 24, 2012)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Enrolled	Active	Completed Baseline Assessment	Completed 1-mo follow-up	Completed 3-month follow-up	Completed Study	Lost to Follow-up	# AEs
Total (all sites):	**404**	**80**	**40**	**284**	**105**	**200**	**146**	**104**	**65**	**114**	**7**
Bronx	16	1	2	13	9	9	5	2	0	4	0
Denver	87	9	3	75	19	59	47	37	24	32	1
Long Beach	43	3	7	33	22	19	11	2	-	11	1
Manhattan	95	27	15	53	18	31	16	16	10	25	2
Milwaukee	52	11	6	34	20	28	22	16	7	7	1
Philadelphia	92	25	5	62	10	45	39	29	23	29	1
Portland	20	4	2	13	6	8	6	2	1	6	1
San Diego	1	0	0	1	1	1	-	-	-	0	0

APPENDIX B continued
SAFEVET Adverse Events Log (As of September 24, 2012)

Site	Date of Event	Date Discovered	Date Reported to Local IRB	Related to Study	Expected/ Unexpected	Description
Manhattan	2/17/2011	2/18/2011	2/25/2011	No	Yes	Suicide Attempt
Philadelphia	7/13/2011	7/29/2011	7/29/2011	No	No	Hit by Train Resulting in Death
Denver	8/2/2011	8/5/2011	8/8/2011	No	Yes	Suicide Attempt Resulting in Death
Portland	4/26/2012	5/24/2012	5/29/2012	No	Yes	Suicide Attempt
Milwaukee	5/15/2012	5/15/2012	5/21/2012	No	No	Suicidal Ideation/Homicidal Ideation
Manhattan	5/10/2012	5/24/2012	5/31/2012	No	Yes	Suicide Attempt
Long Beach	6/27/2012	6/27/2012	7/3/2012	No	Yes	Suicidal Ideation leading to inpatient hospitalization

APPENDIX C
SAFEMIL Enrollment Report and Adverse Event Log (As of September 24, 2012)

	Assessed for Eligibility	Ineligible	Eligible but Refused Entry into Study	Eligible but not Enrolled – Other Reasons	Enrolled	Active	Completed Baseline Assessment	Completed Discharge Assessment	Completed 1-month follow-up	Completed Study	Lost to Follow-up	# AEs
SAFEMIL	175	49	26	33	67	40	67	58	43	26	1	4

SAFEMIL Adverse Events Log (As of September 24, 2012)

Date of Event	Date Discovered	Date Reported to Local IRB	Related to Study	Expected/ Unexpected	Description
10/4/2011	10/5/2011	10/5/2011	No	Yes	Suicide Ideation leading to involuntary hospitalization
10/1/2011	11/2/2011	11/2/2011	No	No	Participant in federal custody
12/3/2011	12/4/2011	12/6/2011	No	Yes	Admitted to inpatient unit for possible suicide ideation, cutting behaviors, and high blood alcohol content.
10/11/2011	11/8/2011	11/9/2011	No	Yes	Depression leading to voluntary psychiatric hospitalization

APPENDIX D
SAFEVET and SAFEMIL Participants Lost to Follow-up (As of September 24, 2012)

SAFEVET Reasons for Participants Lost to Follow-up

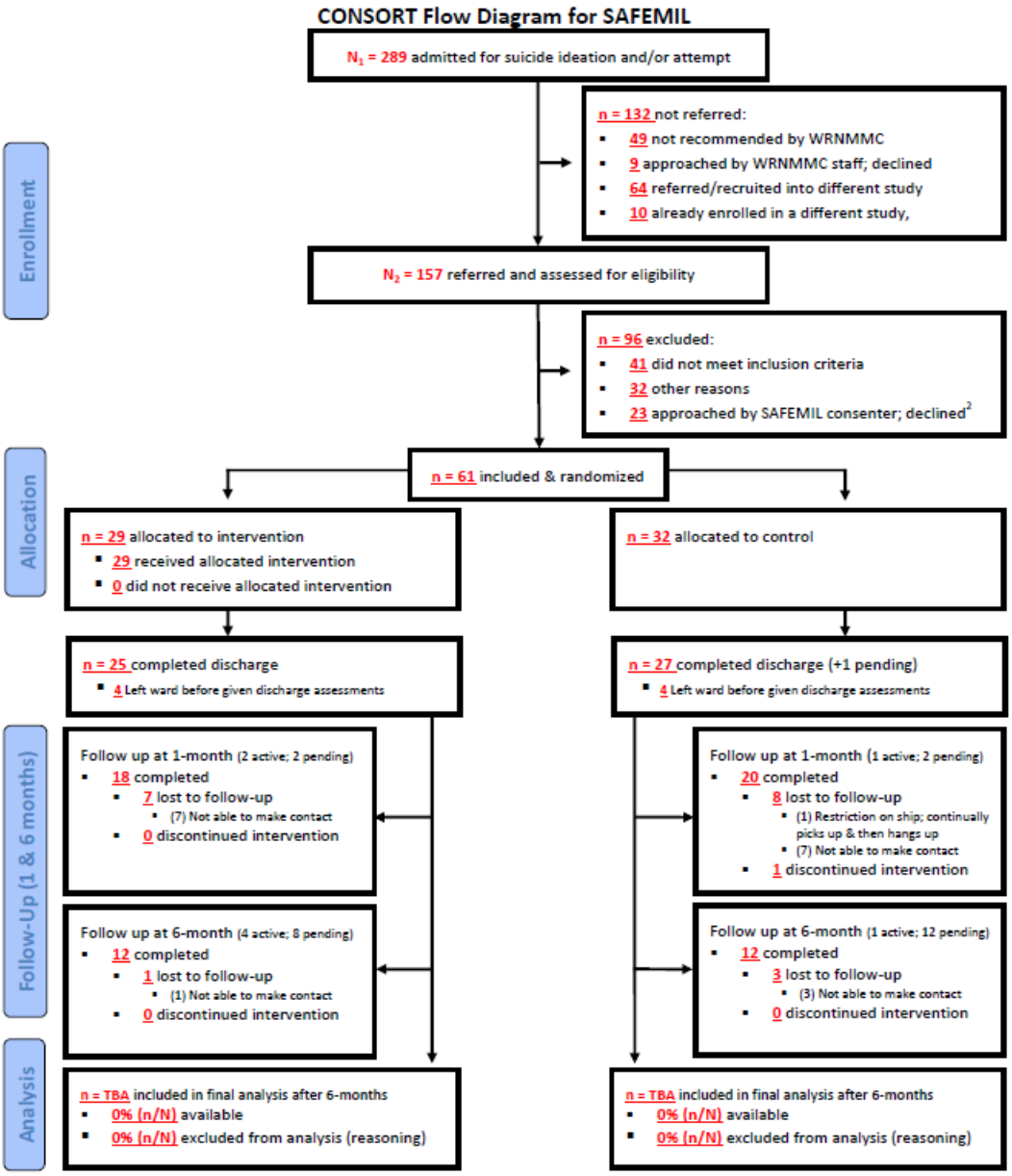
114	Total # of subjects lost to follow-up
68	Withdrawn because did not complete baseline assessment
20	Did not complete 6-month follow-up assessment
9	Subjects withdrew because no longer interested in participating
5	Subjects withdrew because no longer comfortable with study
3	Subjects withdrew because too busy to complete assessments
2	Subjects deceased
2	Feels that the assessments are too long
2	Did not meet entry criteria
2	No reason given
1	Claims that the assessment questions are not pertinent to him

SAFEMIL Reasons for Participants Lost to Follow-up (SAFEMIL)

1	Total # of subjects lost to follow-up
1	Withdrawn because participant was imprisoned

Appendix E
SAFEMIL CONSORT Diagram – Since Last Annual Report

September 25th, 2011–September 24th, 2012



Appendix F
SAFEMIL Baseline Demographic Data

Table 1. Sample Demographics for SAFEMIL (N = 67)*	**Treatment (n = 34)**	**Control (n = 33)**
Age, mean (SD), years	28.7 (10.0)	32.7 (9.8)
Gender		
Male	25 (73.5)	21 (63.6)
Female	9 (26.5)	12 (36.4)
Race/Ethnicity		
American Indian/Alaska Native	0	0
Asian	-	
Black/African-American	4 (11.8)	2 (6.1)
Hispanic/Latino	2 (5.9)	3 (9.1)
Native Hawaiian/Other Pacific Islander	-	
White	25 (73.5)	24 (72.7)
Multi-racial	3 (8.8)	3 (9.1)
Other	0	1 (3.0)
Education		
No high school education	0	0
High school diploma/equivalent	11 (32.4)	5 (15.2)
Higher studies	23 (67.6)	28 (84.8)
Marital Status		
Single	16 (47.1)	9 (27.3)
Cohabitating	2 (5.9)	0
Married	9 (26.5)	13 (39.4)
Separated/Divorced/Widowed	6 (17.6)	10 (30.3)
No response	1 (2.9)	1 (3.0)
Military Deployment		
Yes	19 (55.9)	23 (69.7)
No	15 (44.1)	9 (27.3)
No response	0	1 (3.0)
Military Combat		
Yes	8 (23.5)	11 (33.3)
No	26 (76.5)	21 (63.6)
No response	0	1 (3.0)

* Data presented as No. (%), except as noted

Appendix G
SAFEMIL Baseline Suicide Attempt Data

Table 2: Suicide Attempt Status at Time of Hospitalization

	Treatment (n = 34)	**Control (n = 33)**
Suicide Attempts		
Yes	16 (47.1)	17 (51.5)
No	18 (52.9)	16 (48.5)

Table 3: Number of Prior Suicide Attempts

	Treatment (n = 34)	**Control (n = 33)**
No. of Suicide Attempts		
0	18 (52.9)	16 (48.5)
1	9 (26.5)	11 (33.3)
2	6 (17.6)	4 (12.1)
3	1 (2.9)	1 (3.0)
4	0	1 (3.0)